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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,690	08/28/2003	Joanne Young Hee Kwak Kim	112461-016	9043

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EXAMINER
SZPERKA, MICHAEL EDWARD

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/651,690	KIM ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-276* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-276* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Prior to setting forth the restriction requirement, it is noted that the claims are drawn to patentably distinct methods and products. Claims reciting methods to inhibit spontaneous abortion or implantation failure appear to target disparate pathways known to alter T cell function using products that differ in structure to such an extent that they are considered separately patentable. Similarly, claims drawn to pharmaceutical compositions for use in inhibiting spontaneous abortion or implantation failure are so constructed as to encompass patentably distinct products with different structures and modes of action. Additionally, product claims 266-268 and 274-276 for a diagnostic kit are improperly dependent on method claims in their current form and as such have been grouped with the other claims involving a diagnostic kit. Therefore, the restriction will be set forth for each of the various groups, irrespective of format of the claims.

Upon election, applicant is requested to amend the claims to set forth the elected inventive group.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-21 and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an antibody specific for CD80, classified in Class 424, subclass 141.1.

II. Claims 1-20, 22, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an antibody specific for CD86, classified in Class 424, subclass 141.1.

III. Claims 1-20, 23, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an antibody specific for ICOS, classified in Class 424, subclass 144.1.

IV. Claims 1-20, 24, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an soluble form of CD28, classified in Class 514, subclass 8.

V. Claims 1-20, 25, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an soluble form of a ICOS, classified in Class 514, subclass 8.

VI. Claims 1-20, 26, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an soluble form of CTLA-4, classified in Class 514, subclass 8.

VII. Claims 1-19, 27, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using immunostimulatory nucleic acid, classified in Class 514, subclass 44.

VIII. Claims 1-19, 28-35, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an antibody specific for IL-1, classified in Class 424, subclass 145.1.

IX. Claims 1-19, 28-35, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using a receptor that binds IL-1, classified in Class 424, subclass 184.1.

X. Claims 1-19, 28-35, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an agent that inhibits the biosynthesis of IL-1, classified in Class 424, subclass 184.1.

XI. Claims 1-19, 28-35, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an antibody specific for IL-2, classified in Class 424, subclass 145.1.

XII. Claims 1-19, 28-35, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using a receptor that binds IL-2, classified in Class 424, subclass 184.1.

XIII. Claims 1-19, 28-35, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an agent that inhibits the biosynthesis of IL-2, classified in Class 424, subclass 184.1.

XIV. Claims 1-19, 28-35, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an antibody specific for INF-γ, classified in Class 424, subclass 145.1.

XV. Claims 1-19, 28-35, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using a receptor that binds INF-γ, classified in Class 424, subclass 184.1.

XVI. Claims 1-19, 28-35, and 43-52, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an agent that inhibits the biosynthesis of INF-γ, classified in Class 424, subclass 184.1.

XVII. Claims 1-19, 28, 30-33, 36, 38-40, 43-65, 67-69, 73-78, 80-82, 86-111, 139-163, 165-175, and 177-187, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using an antibody to TNF-α, classified in Class 424, subclass 145.1.

XVIII. Claims 1-19, 28, 30-31, 34, 37, 43-64, 66, 73-77, 79, and 113-137, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using a soluble TNF-α receptor, classified in Class 424, subclass 184.1.

XIX. Claims 1-19, 28-29, 41, 43-64, 70, 73-77, 83, and 189-200, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using a thalidomide analog, classified in Class 424, subclass 184.1.

XX. Claims 1-19, 28-29, 42-64, 71, 73-77, 84, and 202-210, drawn to a method of treatment that inhibits spontaneous abortion or implantation failure using a phosphodiesterase type IV inhibitor, classified in Class 424, subclass 184.1.

XXI. Claims 72, 85, 112, 164, 176, and 188, drawn to a pharmaceutical composition comprising an antibody to TNF-α, classified in Class 424, subclass 145.1.

XXII. Claims 72, 85, and 138, drawn to a pharmaceutical composition comprising a soluble TNF-α receptor, classified in Class 424, subclass 184.1.

XXIII. Claims 72, 85, and 201, drawn to a pharmaceutical composition comprising a thalidomide analog, classified in Class 424, subclass 184.1.

XXIV. Claims 72, 85, and 211, drawn to a pharmaceutical composition comprising a phosphodiesterase type IV inhibitor, classified in Class 424, subclass 184.1.

XXV. Claims 212-233, drawn to a method for diagnosing infertility, classified in Class 435, subclass 7.1.

XXVI. Claims 234-239, 266-268, and 274-276, drawn to a diagnostic kit, classified in Class 435, subclass 810.

XXVII. Claims 240-265 and 269-273, drawn to a method for determining the efficacy of treatment, classified in Class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions (XXI-XXIV and I-XX) and (XXVI and XXV/XXVII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical compounds of Groups XXI-XXIV can be used to alter

the reactivity of T cells for purposes other than inhibiting spontaneous abortion or implantation failure, while the diagnostic kit of Group XXVI could be used to determine the level of Th1 and Th2 immune responses in settings other than infertility.

3. Inventions I-XX, XXV, and XXVII are different methods that require different process steps, contain different ingredients, and achieve different ends. Therefore they are patentably distinct.

4. Inventions XXI-XXIV and XXVI are different products that have distinct structures and modes of action, thus rendering them patentably distinct.

5. Because these inventions are distinct for the reasons given above, and the literature searches required for Groups I-XXVII are divergent, and Groups I-XXVII have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to patentably distinct species of the claimed inventions of Groups I-XX and XXV-XXVII with regards to the methods of measuring cytokines. The source of the cytokines that are measured can be either:

A) in serum, or

B) intracellular.

These species are patentably distinct because the methods require different reagents and process steps and can potentially yield different data since the population of cells used for intracellular staining may not be responsible for production of all the cytokines found in serum.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5, 219, 238, and 247 are generic for example.

7. This application also contains claims directed to patentably distinct species of the claimed inventions of Groups I-XX and XXV-XXVII with regards to the identity of the Th1 and Th2 cytokines that are claimed. The Th1 cytokines are:

A) IL-1,

B) IL-2,

C) TNF-α,

D) INF-γ, or

E) combination of the above.

The Th2 cytokines are:

A) IL-4,

B) IL-5,

C) IL-6,

D) IL-10, or

E) a combination of the above.

These species are distinct because they differ in their structure and their effect upon target cell populations, thus making them separate and patentably distinct species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of Th1 cytokines and a single disclosed species of Th2 cytokines for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5, 219, 238, and 247 are generic for example.

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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